application. On December 20, 1995, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before May 12, 1997, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: March 17, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–9432 Filed 4–10–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposals for the collection of information. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicaid, EPSDT, Maternal and Child Health; *Form No.:* HCFA–416; *Use:* States are required to submit annual EPSDT program reports to HCFA pursuant to Section 1902(a) (43) of the Social Security Act. These reports provide HCFA with data necessary to assess the effectiveness of State EPSDT programs, to develop trend patterns and projections nationally, and respond to inquiries. Respondents are State Medicaid agencies; *Frequency:* Annually; *Affected Public:* State, local or tribal government; *Number of Respondents:* 56; *Total Annual Responses:* 56; *Total Annual Hours:* 1,568.

To request copies of the proposed paperwork collection referenced above, E-mail your request, including your address, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections should be sent within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Financial and Human Resources, Management Analysis and Planning Staff, Attention: Linda Mansfield, Room C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: April 2, 1997.

Edwin J. Glatzel,

Director, Management Analysis and Planning Staff, Office of Financial and Human Resources, Health Care Financing Administration.

[FR Doc. 97–9356 Filed 4–10–97; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Special Project Grants; Traumatic Brain Injury Demonstration Grants

AGENCY: Health Resources and Services Administration (HRSA).

ACTION: Notice; correction.

SUMMARY: The Health Resources and Services Administration published a document in the **Federal Register** of March 27, 1997, concerning Special Project Grants; Traumatic Brain Injury Demonstration Grants. The document contained an incorrect phone number for the Division of Maternal, Infant, Child and Adolescent Health (DMICAH).

Correction

In the **Federal Register** issue of Thursday, March 27, 1997 (62 FR 14684), in FR Doc. 97–7727, on page 14685 in the second column, correct the **FOR FURTHER INFORMATION CONTACT** caption to read:

FOR FURTHER INFORMATION CONTACT: Requests for technical or programmatic information from MCHB should be directed to the Division of Maternal, Infant, Child and Adolescent Health (DMICAH), Maternal and Child Health Bureau, Health Resources and Services Administration, Room 18A–39, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857. The DMICAH telephone number for TBI inquiries is 301–443–5599.

The rest of the notice remains the same.

Dated: April 7, 1997.

Claude Earl Fox,

Acting Administrator.

[FR Doc. 97–9337 Filed 4–10–97; 8:45 am]

BILLING CODE 4160–15–P